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TRANSMITTAL FORM

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Total Number of Pages in This Submission: 42

Application Number	10/612,784
Filing Date	07-02-2003
First Named Inventor	WASIELEWSKI, RAY C.
Art Unit	3738
Examiner Name	SNOW, BRUCE E.
Attorney Docket Number	ORW01-GN004

ENCLOSURES *(Check all that apply)*

- [✓] Fee Transmittal Form
  - [ ] Fee Attached
- [ ] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Reply to Missing Parts/ Incomplete Application
  - [ ] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
  - [ ] Landscape Table on CD
- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [✓] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [✓] Other Enclosure(s) (please Identify below):
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Remarks

FEE TRANSMITTAL (DUP) AND APPEAL BRIEF (38 PGS)

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	TAFT STETTINIUS & HOLLISTER LLP		
Signature			
Printed name	RYAN L. WILLIS		
Date	07-10-2008	Reg. No.	48,787

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Signature	Sharon A. Shelton		
Typed or printed name	SHARON A. SHELTON	Date	07-10-2008

PTO/SB/17 (10-07)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2008

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT	($)	970.00

Complete if Known	
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First Named Inventor	WASIELEWSKI, RAY C.
Examiner Name	SNOW, BRUCE E.
Art Unit	3738
Attorney Docket No.	ORW01-GN004

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☑ Deposit Account Deposit Account Number: 50-3072 Deposit Account Name: TAFT STETTINIUS & HOLLIST

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
		Small Entity		Small Entity		Small Entity	
Application Type	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fees Paid ($)
Utility	310	155	510	255	210	105	
Design	210	105	100	50	130	65	
Plant	210	105	310	155	160	80	
Reissue	310	155	510	255	620	310	
Provisional	210	105	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	210	105
Multiple dependent claims	370	185

Total Claims	Extra Claims	Fee ($)	Fee Paid ($)
_____ - 20 or HP =	_____	x _____	= _____

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims	Extra Claims	Fee ($)	Fee Paid ($)
_____ - 3 or HP =	_____	x _____	= _____

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims	
Fee ($)	Fee Paid ($)
_____	_____

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $260 ($130 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee ($)	Fee Paid ($)
_____ - 100 =	_____ / 50 =	_____ (round up to a whole number)	x _____	= _____

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other (e.g., late filing surcharge): (1402) APPEAL BRIEF FILING FEE; (1252) 2-MO EXTN FEE	970.00

SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 48,787	Telephone 513-357-9663
Name (Print/Type)	RYAN L. WILLIS		Date 07-10-2008

PTO/SB/17 (10-07)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Effective on 12/08/2004.
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FEE TRANSMITTAL
For FY 2008

☐ Applicant claims small entity status. See 37 CFR 1.27

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Examiner Name	SNOW, BRUCE E.
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Attorney Docket No.	ORW01-GN004

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☑ Deposit Account Deposit Account Number: 50-3072 Deposit Account Name: TAFT STETTINIUS & HOLLIST

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Design	210	105	100	50	130	65	
Plant	210	105	310	155	160	80	
Reissue	310	155	510	255	620	310	
Provisional	210	105	0	0	0	0	

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HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims Fee ($)	Multiple Dependent Claims Fee Paid ($)
_____	_____

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Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee ($)	Fee Paid ($)
_____ - 100 =	_____ / 50 =	_____ (round up to a whole number)	x _____	= _____

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other (e.g., late filing surcharge): (1402) APPEAL BRIEF FILING FEE; (1252) 2-MO EXTN FEE	970.00

SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 48,787	Telephone 513-357-9663
Name (Print/Type)	RYAN L. WILLIS		Date 07-10-2008

CERTIFICATE OF MAILING

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7/10/2008
Date

Sharon Shelton
Sharon Shelton

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:

Appellant	:	Wasielewski, Ray C.
Filed	:	July 2, 2003
Serial No.	:	10/612,784
Title	:	USE OF SNAP-ON SEMI ANNULAR ACETABULAR
	:	COMPONENT AUGMENTS TO INHIBIT MULTI-
	:	DIRECTIONAL INSTABILITY AFTER THA
Docket No.	:	ORW01-GN004
Examiner	:	Snow, Bruce E.
Art Unit	:	3738

Hon. Commissioner for Patents
Alexandria, VA 22313

Dear Sir:

APPEAL BRIEF

This is an appeal from the final Office action mailed December 17, 2007. Appellant submitted a timely Notice of Appeal on March 10, 2008. An Advisory action was mailed on March 17, 2008. Accordingly, the instant Appeal Brief is timely submitted with a two-month extension of time fee.

TABLE OF CONTENTS

(1) Real Party in Interest

Orthowaz, Ltd., is the real party in interest by way of assignment from Ray C. Wasielewski, recorded on reel 016328, frame 0007. This application has been exclusively licensed to Zimmer, Inc., a manufacturer and seller of joint replacement components (www.zimmer.com).

(2) Related Appeals and Interferences

Appellant and Appellant's representative are not aware of any other appeal or interference that will directly affect, would be directly affected by, or would have a bearing on the Board's decision in the instant appeal.

(3) Status of the Claims

Claims 1, 2, 4-6, 14, 15, 27-32, and 37-39 are pending. Of the pending claims, 38 and 39 have been withdrawn from consideration. Claims 3, 7-13, 16-26, 33-36, 40-108, 109, and 110 have been canceled. Claims 1, 2, 4-6, 14, 15, 27-32, and 37 stand rejected. Appellant is appealing the rejections of claims 1, 2, 4-6, 14, 15, 27-32, and 37.

(4) Status of Amendments

The claims on appeal comprise those claims filed pursuant to the After Final Amendment on April 24, 2008. This April 24 After Final Amendment apparently has not been acted upon by Examiner as Appellant has failed to receive any indication whether this Amendment will or will not be entered. Appellant asserts entry of the After Final Amendment is appropriate as the only change from the October 11, 2007 Amendment includes the cancellation of claim 109. PAIR, as of July 9, 2008, did not indicate any action had been taken by the Examiner on this April 24 Amendment.

Appellant also filed a February 19, 2008 After Final Amendment that was denied entry by the Examiner on March 17, 2008.

(5) Summary of the Claimed Subject Matter

Each of the two independent claims on appeal, claims 1 and 27, is segmented below. The claim limitations appear in bold text, followed by italicized citations to support found in the specification of the application as originally filed.

Claim 1

Claim 1 is directed to a prosthetic device for use with a hip replacement prosthesis that includes an acetabular cup assembly to be fastened to a patient's pelvis and a femoral stem to be fastened to the patient's femur, where the femoral stem includes a ball component at its proximal end received within the acetabular cup assembly to form a ball joint type coupling, the prosthetic device comprising:

an acetabular liner for releasably engaging an acetabular cup permanently mounted to the patient's pelvis *(Support for this limitation is found in the application as originally filed in [0029], [0030], [0031], [0032], [0035], [0038], original claim 13, and original claim 51. See also Fig. 4 (24, referencing an acetabular liner; 10, referencing an acetabular cup).)*; **and**

a semiannular augment to be mounted to a rim of an acetabular liner of a hip replacement prosthesis, wherein the semiannular augment assists in improving stability of a ball joint type coupling by increasing the height of a portion of the rim of the acetabular liner, at least temporarily, between the acetabular liner and a femoral stem of the hip replacement prosthesis while allowing rotational and angular movement between the acetabular cup assembly and the femoral stem *(Support for this limitation is found in the application as originally filed in [0002], [0006], [0007], [0008], [0009], [0010], [0013], [0014], [0029], [0030], [0031], [0033], [0034], [0035], [0036], [0037], [0038], [0039], original claim 1, original claim 27, original claim 54, original claim 101, and the Abstract. See also Fig. 4 (26a, referencing a semiannular augment; 18, referencing a ball of a femoral prosthetic))*;

the semiannular augment being formed from an augment material comprising at least one of a biologic material, a biologically absorbable material, and a combination of biologic and biologically absorbable materials *(Support for this limitation is found in the application as originally-filed in [0002], [0006], [0007], [0008], [0009], [0011], [0012], [0013], [0025], [0026], [0027], [0029], [0030], [0039], [0040], [0041], [0042], [0043], [0044], [0045], [0046], [0047], original claim 1, original claim 27, original claim 82, original claim 91, and the Abstract.)*; **and**

wherein the augment material is supplemented with at least one of an agent to promote the formation of scar tissue, a clotting agent, and an antibacterial agent *(Support for this limitation is found in the application as originally-filed in [0006], [0044], [0045], [0047], original claim 16,original claim 17,original claim 18, original claim 37, original claim 38, original claim 39, original claim 68, original claim 69, original claim 70, original claim 79, original claim 80, original claim 81, original claim 88, original claim 89, original claim 90, original claim 95, and original claim 98.)*; **and**

wherein the augment material is formulated not to transform into scar tissue *(Support for this limitation is found in the application as originally-filed in [0007], [0026], [0040], [0046], original claim 19, original claim 20, original claim 40, original claim 41, original claim 77, original claim 78, original claim 86, original claim 87, original claim 96, original claim 99, original claim 100, original claim 107, and original claim 108.)*.

Claim 27

Claim 27 is directed to a hip prosthesis comprising:

an acetabular cup assembly to be fastened to a patient's pelvis, the acetabular cup assembly including *(Support for this limitation is found in the application as originally-filed in [0002], [0007], [0008], [0009], [0013], [0014], [0017], [0020], [0021], [0023], [0029], [0033], [0034], original claim 1, original claim 27, original claim 91, original claim 101, and*

the Abstract. See also Fig. 4 (10, referencing an acetabular cup; 24', referencing an insert bearing) and Fig. 7 (10, referencing an acetabular cup; 24", referencing an insert bearing)):

an acetabular liner *(Support for this limitation is found in the application as originally-filed in [0004], [0029], [0030], [0035], [0038], original claim 13, and original claim 51. See also Fig. 4 (24', referencing an insert bearing) and Fig. 7 (24", referencing an insert bearing))*; **and**

an acetabular cup, the acetabular liner releasably engaging the acetabular cup to be permanently mounted to the patient's pelvis *(Support for this limitation is found in the application as originally-filed in [0003], [0008], [0009], [0013], [0014], original claim 1, original claim 27, original claim 91,and original claim 101. See also Fig. 1 (10, referencing an acetabular cup), Fig. 4 (10, referencing an acetabular cup; 24', referencing an insert bearing), and Fig. 7 (10, referencing an acetabular cup; 24'', referencing an insert bearing))*;

a femoral stem to be fastened to the patient's femur, the femoral stem including a ball component at its proximal end received within the acetabular liner to form a ball joint type coupling *(Support for this limitation is found in [0003], [0008], [0009], [0010], [0011], [0013], [0014], [0034], original claim 1, original claim 27, original claim 91, and original claim 101. See also Fig. 1 (18, referencing a ball component of a femoral member))*; **and**

a semiannular augment to be mounted to a distal end of the acetabular liner, adjacent to the ball component, wherein the semiannular augment assists in stabilizing the ball joint type coupling between the acetabular liner and the femoral stem by temporarily increasing the height of a portion of the rim of the acetabular liner, while enabling rotational and angular movement between the acetabular liner and the femoral stem *(Support for this limitation is found in the application as originally-filed in [0002], [0006], [0007], [0008], [0009], [0010], [0011], [0013], [0014], [0029], [0030], [0031], [0032], [0033], [0034], [0035], [0036], [0037], [0038], [0039], original claim 1, original claim 27, original claim 91, original claim 101, and the Abstract.)*;

the semiannular augment being formed from an augment material comprising at least one of a biologic material, a biologically absorbable material, and a combination of biologic and biologically absorbable materials *(Support for this limitation is found in the application as originally-filed in [0002], [0006], [0007], [0008], [0009], [0011], [0012], [0013], [0025], [0026], [0027], [0029], [0030], [0039], [0040], [0041], [0042], [0043], [0044], [0045], [0046], [0047], original claim 1, original claim 27, original claim 82, original claim 91, and the Abstract.)*; **and**

wherein the semiannular augment includes at least one integrated fastener *(Support for this limitation is found in the application as originally-filed in [0006], [0032], [0039], [0041], original claim 14, original claim 15, and original claim 67. See also Fig. 4 (28, referencing male couplings), Fig. 5 (28, referencing male couplings), and Fig. 7 (28, referencing male couplings))*; **and**

wherein the augment material is formulated not to transform into scar tissue *(Support for this limitation is found in the application as originally-filed in [0007], [0026], [0040], [0046], original claim 19, original claim 20, original claim 40, original claim 41, original claim 77, original claim 78, original claim 86, original claim 87, original claim 96, original claim 99, original claim 100, original claim 107, and original claim 108.)*.

(6) Grounds of Rejection and Objection to be Reviewed on Appeal

Appellant is appealing four grounds of rejection recited in the December 17, 2007, final Office action. The issues to be reviewed on appeal are:

1) Has the Examiner carried his burden to prove that claims 1, 2, 4-6, 14, 15, 27-32, and 37 fail to particularly point out and distinctly claim the subject matter of the invention pursuant to 35 U.S.C. § 112, second paragraph?

2) Has the Examiner carried his burden to prove that claims 1, 2, 4-6, 14, 15, 27-32, and 37 fail to comply with the written description requirement of 35 U.S.C. § 112, first paragraph?

3) Has the Examiner carried his burden to prove that claims 1, 2, 4-6, 14, 15, 27-32, and 37 are unpatentable over Klüber (DE 19716051) under 35 U.S.C. § 102(b)?

4) Has the Examiner carried his burden to prove that claims 1, 2, 4-6, 14, 15, 27-32, and 37 are unpatentable over Klüber alone, or in combination with Mikhail (US 5,549,701), under 35 U.S.C. § 103(a)?

(7) Argument

I. Claims 1, 2, 4-6, 14, 15, 27-32, and 37 particularly point out and distinctly claim the subject matter of the invention in compliance with 35 U.S.C. § 112, second paragraph.

Claims 1, 2, 4-6, 14, 15, 27-32, and 37[1] stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Appellant respectfully submits each of these claims is definite in accordance with 35 U.S.C. § 112, second paragraph.

The final Office action states:

> Regarding claim 1, "*wherein the augment material is formulated not to transform into scar tissue*" is still ambiguous. The paragraph before claims, "*wherein the augment material is supplemented with at least one of an agent to promote the formation of scar tissue*".[2]

Similarly, the final Office action states:

> Regarding claims 1, 27 and 29, "*wherein the augment is formulated not to transform into scar tissue*" is indefinite. Note that each claim allows the augment to be a biologically absorbable material. Why does applicant's augment, made from the same material, not transform into scar tissue?[3]

The final Office action appears to base this ground of rejection on erroneous conflations of distinct characteristics of the claimed augment material. First, the Examiner melds the recitation in the claims of an augment material: (1) formulated not to transform into scar tissue; and (2) formulated from a biologically absorbable material. But a material that is biologically absorbable need not transform into scar tissue. Accordingly, these limitations are separate and distinct from one another. Second, the Examiner incorrectly concludes that supplementing an augment material "with at least one of an agent to promote the formation of scar tissue"

[1] Although the final Office action also purports to reject claims 38 and 39 under 35 U.S.C. § 112, paragraph 2, claims 38 and 39 were withdrawn by the Examiner from consideration in 2005 and, thus, cannot properly be rejected.
[2] December 17, 2007, final Office action, page 4.
[3] December 17, 2007, final Office action, page 4.

mandates that the augment material *itself* transform into scar tissue. Simply put, promoting the formation of scar tissue and transforming into scar tissue are distinct characteristics. Stated another way, a material may promote the formation of scar tissue without transforming into scar tissue. A brief analogy may be helpful in understanding the distinctions of these limitations.

In the chemical arts, a catalyst is a substance that causes or accelerates a chemical reaction without itself being affected. In other words, the catalyst impacts the rate of a chemical reaction, but is neither a reactant nor a product. Analogous to the instant application, the augment material can be thought of as a catalyst by incorporating an agent promoting scar tissue formation, but the actual augment material itself does not transform into scar tissue (i.e., not a component of the overall reaction product). Simply put, the erroneous conflation of these concepts (forming scar tissue vs. promoting scar tissue formation) is the foundation upon which the Examiner's ground of rejection is built. Consequently, this ground of rejection is clearly erroneous and should be reversed.

Appellant's claims plainly require an augment material that "is formulated not to transform into scar tissue" and that "is supplemented with at least one of an agent to promote the formation of scar tissue." Nothing about these recitations is indefinite. They reasonably apprise those skilled in the art of both the utilization and scope of the invention and the claim language is as precise as the subject matter permits.[4] Thus, Appellant's claims particularly point out and distinctly claim the subject matter which Appellant regards as the invention in accordance with 35 U.S.C. § 112, second paragraph. Because the Examiner has failed to carry his burden to show that claims 1, 2, 4-6, 14, 15, 27-32, and 37 fail to comply with 35 U.S.C. § 112, second paragraph, reversal of this ground of rejection is merited and respectfully requested.

[4] *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, (Fed. Cir. 1985) citing *Georgia-Pacific Corp. v. United States Plywood Corp.*, 258 F.2d 124, 136 (2nd Cir.), cert. denied, 358 U.S. 884 (1958).

II. Claims 1, 2, 4-6, 14, 15, 27-32, and 37 comply with the written description requirement of 35 U.S.C. § 112, first paragraph.

Claims 1, 2, 4-6, 14, 15, 27-32, and 37[5] stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.[6] More specifically, the final Office action asserts the element of claim 1 reciting "wherein the augment is formulated not to transform into scar tissue" is new matter and states, "[t]he specification does not support a material that does not transform into scar tissue but contains an agent to promote scar tissue."[7] Appellant respectfully asserts the rejection of claims 1, 2, 4-6, 14, 15, 27-32, and 37 under 35 U.S.C. § 112, first paragraph, is improper and should be reversed for at least the following reasons.

First, Appellant points out the Examiner's failure to carry his burden by making the requisite showing that the disclosure is inadequate to support the subject matter claimed and, thus, the Examiner has not overcome the presumption that the description is adequate. Notably, M.P.E.P. § 2163.04 states:

> A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. . . . The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims.

Regarding claim 1, the entirety of the final Office action's showing is a single conclusory statement: "The specification does not support a material that does not transform into scar tissue but contains an agent to promote scar tissue."[8] Regarding claims 27 and 29, the entirety of the

[5] Although the December 17, 2007, final Office action also purports to reject claim 110 under 35 U.S.C. § 112, paragraph 1, claim 110 was canceled in the Amendment filed October 11, 2007, and, thus, cannot properly be rejected.
[6] Final Office action page 5.
[7] Final Office action page 5.
[8] Final Office action page 5.

final Office action's showing is a single conclusory statement: "Regarding claims 27 and 29, 'wherein the augment is formulated not to transform into scar tissue' is new matter."[9]

It is beyond reasonable dispute that neither of these statements properly satisfies the Examiner's "initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims."[10] In addition to failing to satisfy the preponderance of the evidence standard required for these written description rejections, the Examiner's refusal to set out the basis for these rejections has negated Appellant's opportunities to fully refute these conclusory allegations and unfortunately given the Board a *de minimus* factual record for consideration on appeal. In view of these mere conclusory allegations, it is clear that the Examiner has failed to carry his burden of presenting factual evidence as to why one skilled in the art would find Appellant's description insufficient to support the subject matter claimed. Accordingly, the rejections of claims 1, 2, 4-6, 14, 15, 27-32, and 37 under 35 U.S.C. § 112, first paragraph, should be reversed.

Second, even assuming that the Examiner's conclusory statements of rejection fulfilled his initial burden, the Examiner failed to comply with M.P.E.P. § 2163.04 II when he repeated these same conclusory allegations in the final Office action after Appellant called into question these allegations. M.P.E.P. § 2163.04 II requires:

> Upon reply by applicant, before repeating any rejection under 35 U.S.C. 112, para. 1, for lack of written description, [the Examiner must] review the basis for the rejection in view of the record as a whole, including amendments, arguments, and any evidence submitted by applicant. . . . If the record still does not demonstrate that the written description is adequate to support the claim(s), repeat the rejection under 35 U.S.C. 112, para. 1, [the Examiner must] fully respond to applicant's rebuttal arguments, and properly treat any further showings submitted by applicant in the reply.

[9] Final Office action page 5.
[10] M.P.E.P. § 2163.04; *see also In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993).

In direct contradiction to the requirements of M.P.E.P. § 2163.04 II, the Examiner's response to the Appellant's arguments consists of a single sentence: "It is the Examiner's position that the augments 'could also be formulated so as to be replaced by tissue (such as scar-tissue)' does not inherently conclude the exact opposite '*wherein the augment material is formulated not to transform into scar tissue.*'" Thus, the rejections of claims 1, 2, 4-6, 14, 15, 27-32, and 37 under 35 U.S.C. § 112, first paragraph, should also be reversed because the Examiner's response to Appellant's rebuttal arguments was grossly deficient.

Third, the rejection of claims 1, 2, 4-6, 14, 15, 27-32, and 37 under § 112, second paragraph, is erroneous on the merits because the specification, as originally filed, supports the relevant claim limitations. At least paragraphs [0025]-[0027], [0029]-[0030], [0039]-[0043] of the specification as originally filed discuss in detail various materials from which the augments may be constructed. Paragraphs [0044]-[0047] of the specification as originally filed discuss in detail various materials, compositions, etc., that may be incorporated into the various materials from which the augments may be constructed.[11] As known to those of skill in the art, some of these materials, compositions, etc., promote the formation of scar tissue. Accordingly, at least these paragraphs of the specification as originally filed clearly teach that "the augment material [may be] supplemented with at least one of an agent to promote the formation of scar tissue."

Further, paragraph [0040] describes, without limitation, several of the possible formulations:

[11] Paragraph [0044] states that "[i]t is also within the scope of the present invention to 'load' (disburse, coat, impregnate, etc.) the biologic and/or biologically reabsorbable materials comprising the snap-on augments 26 and the male fasteners 28 with agents that could hasten or assist in tissue development, assist in clotting, and/or fight infection." Paragraph [0044] then goes on to list examples of such agents.
Paragraph [0045] states that "[i]t is also within the scope of the invention to incorporate growth stimulating factors in the above exemplary embodiments incorporating biologic or biologically reabsorbable materials." Paragraph [0045] goes on to discuss various examples of such growth stimulating factors.
Paragraph [0046] states that "[i]t is also within the scope of the invention to incorporate connective tissue stem cells and progenitors with biologic or biologically reabsorbable materials disclosed in the above embodiments." Paragraph [0046] goes on to discuss examples of such incorporation.
Paragraph [0047] states that "[i]t is also within the scope of the invention to incorporate hematopoietic stem cells and progenitors with the biologic or biologically reabsorbable materials disclosed in the above embodiments." Paragraph [0047] goes on to discuss examples of such incorporation.

> In the exemplary embodiment utilizing the biologically reabsorbable snap-on augments 26, such augments 26 could be formulated to [be] absorbed over a relatively short period (i.e., several weeks or months) and could also be formulated so as to be replaced by tissue (such as scar-tissue) that would provide for long-term hip stability and, hopefully, normal motion. Such formulations of biologic materials are well known by those of ordinary skill in the art.[12]

Thus, the specification as originally filed clearly discloses that the augment material "could also be formulated so as to be replaced by [scar] tissue." If the description was limited to augment materials always replaced by scar tissue, as the Examiner erroneously alleges, the foregoing recitation would be nonsensical. "Could also" clearly acknowledges the alternative of augment materials not transforming into scar tissue.

In addition, one of ordinary skill in the art would readily recognize the claim limitations directed to augments "formulated not to transform into scar tissue" were merely claiming inherent properties of the disclosed formulations. M.P.E.P. § 2163.07(a) states,

> By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite that function, theory or advantage without introducing prohibited new matter.

One of skill in the art would understand the list of the exemplary augment materials disclosed in the originally filed application includes some materials that would transform into scar tissue and others that would not. Further, one of skill in the art would readily understand the listed exemplary agents and growth factors (which may be loaded into the augment materials) in the originally filed application includes formulations which may hasten or assist tissue development. Thus, it is clear the Examiner has failed to carry his burden of presenting factual evidence as to why one skilled in the art would find Appellant's description insufficient to

[12] Emphasis added.

support the subject matter claimed. Accordingly, the Board should reverse the rejections of claims 1, 2, 4-6, 14, 15, 27-32, and 37 under 35 U.S.C. § 112, first paragraph.

III. Claims 1, 2, 4-6, 14, 15, 27-32, and 37 are novel over Klüber.

As explicitly admitted by the Examiner in the two most recent Office actions, Klüber fails to teach every element recited in claims 1, 2, 4-6, 14, 15, 27-32, and 37. Accordingly, Klüber does not anticipate any of claims 1, 2, 4-6, 14, 15, 27-32, and 37.[13]

Group 1: Claims 1, 2, 4-6, 14, and 15

Klüber does not anticipate claim 1, from which claims 2, 4-6, 14, and 15 depend, at least in part because Klüber fails to disclose: (1) "the augment material is supplemented with at least one of an agent to promote the formation of scar tissue, a clotting agent, and an antibacterial agent" and (2) "wherein the augment material is formulated not to transform into scar tissue."

First, claim 1 requires an augment "supplemented with at least one of an agent to promote the formation of scar tissue, a clotting agent, and an antibacterial agent." As mentioned above, the two most recent Office actions explicitly admit Klüber *does not* disclose this limitation: "Regarding at least claim 1, however, Kuber [sic] fails to teach the augment material is supplemented with at least one of an agent to promote the formation of scar tissue, a clotting agent, and an antibacterial agent."[14] Thus, in the Examiner's own words, he has failed to carry his burden in alleging anticipation. Accordingly, the Board should reverse the 35 U.S.C. § 102(b) rejection of claims 1, 2, 4-6, 14, and 15 for at least this reason.

Second, claim 1, from which claims 2, 4-5, 14, and 15 depend, recites "wherein the augment material is formulated not to transform into scar tissue." The final Office action's sole discussion of Klüber's alleged disclosure of this limitation appears only in the following cryptic parenthetical, "(note Kuber [sic] and applicant teach PLLA, see at least applicant's claim 5)".

[13] See, e.g., M.P.E.P. § 2131, in particular the section entitled "TO ANTICIPATE A CLAIM, THE REFERENCE MUST TEACH EVERY ELEMENT OF THE CLAIM", which states that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)."

[14] Office action mailed July 19, 2007, page 6 and final Office action, page 7.

While it is true that PLLA is one of many materials from which the claimed invention may be constructed, it is all but irrelevant that Klüber's luxation ring also includes PLLA.[15]

Klüber teaches that his luxation ring and screws are "made of PLLA" and are "transformed into yielding connective tissue," which the Examiner interprets to be scar tissue.[16] Thus, although Klüber does not disclose the detailed composition of his luxation ring and screws, it is apparent that the luxation ring includes PLLA and is formulated to transform into scar tissue. In direct contrast, Appellant claims an "augment material [that] is formulated not to transform into scar tissue."

Put another way, while Appellant's augment may include PLLA, it is specifically "formulated not to transform into scar tissue." The mere fact that Klüber's device and Appellant's devices may include a single common ingredient is wholly inadequate to justify an anticipation rejection of claim 1 over Klüber. Respectfully, Appellant requests the Board reverse the 35 U.S.C. § 102(b) rejections of claims 1, 2, 4-6, 14, and 15 for at least this additional reason.

Group 2: Claims 27-32 and 37

Klüber does not anticipate claim 27, from which claims 28-32 and 37 depend, because claim 27 recites at least two limitations not disclosed in Klüber: (1) "the semiannular augment includes at least one integrated fastener" and (2) "the augment material is formulated not to transform into scar tissue."

First, claim 27 requires a semiannular augment including "at least one integrated fastener." Despite Appellant's identification of this deficiency of Klüber on numerous occasions,[17] the Examiner has failed to even remotely address Appellant's arguments concerning this deficiency of Klüber. The Examiner's persistent refusal to fully support his grounds of

[15] This single-ingredient, superficial comparison is on par with an observation that both battery acid and baby formula include water. Notwithstanding a common ingredient, battery acid is indisputably not formulated for infant nutrition.
[16] Office action mailed October 24, 2006, pages 5-6.
[17] Amendment filed January 18, 2007, page 24; RCE & Amendment filed July 11, 2007, page 9; Amendment filed October 11, 2007, page 14; and After-Final Amendment filed February 19, 2008; page 14.

rejection for claim 27 under § 102(b) has effectively limited Appellant's opportunities to address this erroneous rejection.[18]

Klüber discloses only the use of independent, separate, and distinct fasteners in the form of screws: "The luxation retaining ring (A) . . . has pre-bored holes (G) to receive Phillips screws (C) with sunken heads." Figures 2 and 4 show the screws installed in the luxation ring and Figure 3 shows the acetabular cup and the luxation ring without the screws. Thus, Klüber does not disclose a semiannular augment including "at least one integrated fastener" as required by claim 27. Accordingly, the rejection of claims 27-32 and 37 as being anticipated by Klüber should be reversed for at least this reason.

Second, claim 27 requires an augment material "formulated not to transform into scar tissue." As discussed above with regard to claim 1, Klüber does not disclose this limitation. Accordingly, the Board should reverse the rejection of claims 27-32 and 37 as being anticipated by Klüber for at least this additional reason.

[18] *See, e.g.*, Office action mailed April 11, 2007, and Office action mailed July 19, 2007, both of which stated, "Regarding the 102/103 rejections in view of Kuber [sic] (DE 19716051, applicant submitted), the Examiner [sic] position is believed to be clearly stated to one having ordinary skill in the art in the grounds of rejection below."

IV. Claims 1, 2, 4-6, 14, 15, 27-32, and 37 are patentable over Klüber.

Claims 1, 2, 4-6, 14, 15, 27-32, and 37 stand improperly rejected as allegedly being obvious over Klüber. It is well known that a claimed invention is unpatentable if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the pertinent art.[19] Obviousness under 35 U.S.C. § 103 is a legal conclusion based on underlying factual determinations.[20] The underlying factual determinations include (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) objective indicia of non-obviousness.[21] But at no time has the Examiner ever addressed all of these factual determinations.

The Federal Circuit has stated that to reject claims in an application under section 103, an examiner must show an unrebutted *prima facie* case of obviousness.[22] "All words in a claim must be considered in judging the patentability of that claim against the prior art."[23] In addition, "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art."[24]

"What the prior art teaches, whether it teaches away from the claimed invention, and whether it motivates a combination of teachings from different references are questions of fact."[25] In *KSR*, the Supreme Court reaffirmed the requirement that an obviousness analysis should be made explicit to facilitate review.[26] "Every case, particularly those raising the issue of obviousness under section 103, must necessarily be decided upon its own facts."[27] "The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art

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[19] 35 U.S.C. § 103(a) (2004).
[20] *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1164, 77 U.S.P.Q.2d 1865, 1869 (Fed. Cir. 2006).
[21] *KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1734 (2007), citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).
[22] *In re Rouffet*, 149 F.3d 1350, 47 U.S.P.Q.2d 1453 (Fed. Cir. 1998).
[23] *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970).
[24] *KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007).
[25] *In re Fulton*, 391 F.3d 1195, 1199-1200, 73 U.S.P.Q.2d 1141, 1144 (Fed. Cir. 2004).
[26] *KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007); *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).
[27] *In re Jones*, 958 F.2d 347, 350, 21 U.S.P.Q.2d 1941, 1943 (Fed. Cir. 1992).

that existed at the time."[28] In this regard, maintaining objectivity in the obviousness inquiry is accomplished by resolving the level of ordinary skill in the art.[29]

A prior art reference that "teaches away" from a given combination may negate a motivation to modify the prior art to meet the claimed invention.[30] "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the appellant."[31] Thus, even if the Examiner makes out a *prima facie* case of obviousness, Appellant may rebut this presumption by showing that the prior art teaches away from the claimed invention.[32]

Group 1: Claims 1, 2, 4-6, 14 and 15

Claim 1, and claims 2, 4-6, 14, and 15 that depend from claim 1, are patentable over Klüber at least because the rejections made by the Examiner fail to consider all of the claim limitations. Further, the foregoing claims are patentable at least in part because Klüber teaches away from the claimed invention. Still further, the foregoing claims are patentable at least in part because the claimed invention diverges from the commonly accepted wisdom in the art. Accordingly, the Examiner has failed to carry his burden of establishing a *prima facie* case of obviousness with respect to the foregoing claims.

The Examiner has not presented a *prima facie* case of obviousness with respect to claims 1, 2, 4-6, 14 and 15 because he has not properly considered all of the claim limitations. Failing to consider a claim limitation is directly contrary to M.P.E.P. § 2143.03, the heading of which is "All Claim Limitations Must Be Considered." Not only is the final Office action's failure to consider all of the claim limitations contrary to the M.P.E.P., but it is also contrary to binding case law: "All words in a claim must be considered in judging the patentability of that claim

[28] *Interconnect Planning Co. v. Feil*, 774 F.2d 1132, 1138, 227 U.S.P.Q. 543, 547 (Fed. Cir. 1985).
[29] *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718, 21 U.S.P.Q.2d 1053, 1057 (Fed. Cir. 1991).
[30] See *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165, 77 U.S.P.Q.2d 1865, 1870 (Fed. Cir. 2006).
[31] *In re Kahn*, 441 F.3d 977, 990, 78 U.S.P.Q.2d 1329, 1338 (quoting *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994)) (internal quotation marks omitted).
[32] *In re Geisler*, 116 F.3d 1465, 1471, 43 U.S.P.Q.2d 1362, 1364 (Fed. Cir. 1997).

against the prior art."[33] In addition, the Examiner's failure to consider all of the claim limitations has hamstrung Appellant's ability to refute the Examiner's position and correspondingly left a gaping hole in the record for appeal.[34] This is particularly true with respect to the conclusions recited as to the teachings of the Klüber prior art.

Specifically, Klüber does not disclose forming the augment from a material that "is formulated not to transform into scar tissue" as required by claim 1. The Final Office action states, "note Kuber [sic] and applicant teach PLLA, see at least applicant's claim 5." As discussed above, with regard to the § 102 rejections, the mere fact that Klüber discloses a single ingredient that may be included in Appellant's augment is irrelevant. In addition, Klüber clearly teaches this his PLLA transforms into scar tissue while Appellant's augments are "formulated not to transform into scar tissue." Thus, it appears that the Examiner has failed to consider this limitation. The rejection of claims 1, 2, 4-6, 14, and 15 under 35 U.S.C. § 103 should be reversed at least because the Examiner has not presented a *prima facie* case of obviousness with regard to claim 1 due to his failure to consider the limitations requiring the augment to be formed from a material that is "formulated not to transform into scar tissue." But this is not the only basis Appellant asserts for reversal.

Klüber also teaches away from the claimed invention. As discussed above, the claims require the augment material to be formulated not to transform into scar tissue. In direct contrast, Klüber teaches that "[t]he resorbable luxation securing ring (A), made of the material PLLA . . . is transformed into yielding connective tissue, which reduces the risk of a luxation also over the long term."[35] In addition, Klüber states that "after about 6 weeks the ring and attaching screws are transformed into flexible native connecting tissue, which provides protection against disclocations, for example in accidents or falls, even long-term."[36] "The resorbability and transformation into flexible native connecting tissue also result in long-term

[33] *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).
[34] See, e.g., M.P.E.P. § 706.07 ("In making the final rejection, all outstanding grounds of rejection of record should be carefully reviewed, and any such grounds relied on in the final rejection should be reiterated. They must also be clearly developed to such an extent that applicant may readily judge the advisability of an appeal unless a single previous Office action contains a complete statement supporting the rejection.")
[35] Klüber, first page, paragraph labeled (57).
[36] Klüber, Description section.

protection against dislocations . . . ."[37] Thus, Klüber only teaches a ring material transforming into scar tissue and implicitly teaches that it would be less desirable if the ring does not transform into scar tissue. As the rejected claims require the augment material to be formulated not to transform into scar tissue, Klüber precisely the opposite of the claimed invention. The 35 U.S.C. § 103 rejections of claims 1, 2, 4-6, 14, and 15 should be reversed for at least this additional reason.

In addition, Klüber's statements regarding the transformation of the ring into scar tissue are demonstrative of the "accepted wisdom in the art" that it would be desirable for the augment material to transform into scar tissue. Appellant's divergence from this accepted wisdom is further evidence of nonobviousness.[38]

For at least these reasons, the rationale set forth in the final Office action would not have motivated one of skill in the art at the time of the invention to modify Klüber to produce the device of claims 1, 2, 4-6, 14, and 15. Accordingly, the Board should reverse of the rejections of claims 1, 2, 4-6, 14, and 15 under 35 U.S.C. § 103(a).

It should also be noted that the Examiner also appears to allege the foregoing claims are invalid by way of a combination of Klüber with U.S. Patent No. 5,549,701 to Mikhail. But Mikhail is cited solely for the proposition of prior art teaching a liner/cup configuration. At no time is Mikhail alleged to address any of the foregoing deficiencies of Klüber. Accordingly, a detailed discussion of Mikhail has been omitted only for purposes of brevity as the erroneous conclusions of the Examiner as to Klüber comprise the primary issues on appeal.

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[37] Klüber, Description section.

[38] *See, e.g.*, M.P.E.P. § 2145 ("The totality of the prior art must be considered, and proceeding contrary to accepted wisdom in the art is evidence of nonobviousness. In re Hedges, 783 F.2d 1038, 228 USPQ 685 (Fed. Cir. 1986) (Applicant's claimed process for sulfonating diphenyl sulfone at a temperature above 127°C was contrary to accepted wisdom because the prior art as a whole suggested using lower temperatures for optimum results as evidenced by charring, decomposition, or reduced yields at higher temperatures.).").

Group 2: Claims 27-32 and 37

The Board should also reverse the rejection of claims 27-32 and 37 under 35 U.S.C. § 103 because the Examiner has failed to present a *prima facie* case of obviousness with regard to these rejected claims. The Examiner has improperly failed to consider all of the claim limitations of claims Claim 27-32 and 37 as required by M.P.E.P. § 2143.03. In particular, claim 27, from which claims 28-32 and 37 depend, recites at least three limitations that are not disclosed in Klüber: (1) "the semiannular augment includes at least one integrated fastener" and (2) "the augment material is formulated not to transform into scar tissue." The Examiner has not adequately addressed these limitations and, therefore, has not presented a *prima facie* case of obviousness.

First, claim 27 requires a semiannular augment including "at least one integrated fastener." As discussed above, Appellant has brought this deficiency of Klüber to the attention of the Examiner on numerous occasions,[39] and the Examiner has provided no substantive rebuttal. As discussed in *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." Accordingly, the Board should reverse the rejection of claims 27-32 and 37 under 35 U.S.C. § 103 over Klüber at least because the Examiner has not presented a *prima facie* case of obviousness with respect to these claims addressing the integrated fastener limitation.

Second, claim 27 requires an augment material "formulated not to transform into scar tissue." As discussed above with regard to claim 1, Klüber fails to disclose this limitation. Moreover, conventional wisdom at the time, as evidenced by Klüber, highlighted the advantages of materials transforming into connective tissue. As a result, any allegation that Appellant's claims are obvious must address how this allegation can coexist with the disclosure of Klüber teaching precisely the opposite. Accordingly, the Board should reverse the rejection of claims 27-32 and 37 under 35 U.S.C. § 103 in view of Klüber at least because the Examiner has failed

[39] Amendment filed January 18, 2007, page 24; RCE & Amendment filed July 11, 2007, page 9; Amendment filed October 11, 2007, page 14; and After-Final Amendment filed February 19, 2008; page 14.

to present a *prima facie* case of obviousness with respect to these claims addressing the formulation not transforming into scar tissue.

In addition, for the same reasons as discussed above with regard to the 35 U.S.C. § 103 rejection of claims 1, 2, 4-6, 14, and 15, Klüber teaches away from the claimed invention. Also, for the same reasons as discussed above with regard to the 35 U.S.C. § 103 rejection of claims 1, 2, 4-6, 14, and 15, Appellant's invention which does not transform into scar tissue was a result of proceeding contrary to the accepted wisdom in the art. For at least these reasons, the rationale set forth in the final Office action would not have motivated one of skill in the art at the time of the invention to modify Klüber to produce the device of claims 27-32 and 37. Accordingly, reversal of the rejections of claims 27-32 and 37 under 35 U.S.C. § 103(a) is warranted.

In sum, the Board should reverse the rejection of claims 27-32 and 37 under 35 U.S.C. § 103 because the Examiner has not presented a *prima facie* case of obviousness due to his failure to consider all of the claim limitations, the fact that Klüber teaches away from the proposed modification, and the fact that the claimed invention reflects a departure from the conventional wisdom in the art.

It should also be noted that the Examiner also appears to allege the foregoing claims are invalid by way of a combination of Klüber with U.S. Patent No. 5,549,701 to Mikhail. But Mikhail is cited solely for the proposition of prior art teaching a liner/cup configuration. At no time is Mikhail alleged to address any of the foregoing deficiencies of Klüber. Accordingly, a detailed discussion of Mikhail has been omitted only for purposes of brevity as the erroneous conclusions of the Examiner as to Klüber comprise the primary issues on appeal.

(8) Claims Appendix

1. A prosthetic device for use with a hip replacement prosthesis that includes an acetabular cup assembly to be fastened to a patient's pelvis and a femoral stem to be fastened to the patient's femur, where the femoral stem includes a ball component at its proximal end received within the acetabular cup assembly to form a ball joint type coupling, the prosthetic device comprising:

an acetabular liner for releasably engaging an acetabular cup permanently mounted to the patient's pelvis; and

a semiannular augment to be mounted to a rim of an acetabular liner of a hip replacement prosthesis, wherein the semiannular augment assists in improving stability of a ball joint type coupling by increasing the height of a portion of the rim of the acetabular liner, at least temporarily, between the acetabular liner and a femoral stem of the hip replacement prosthesis while allowing rotational and angular movement between the acetabular cup assembly and the femoral stem;

the semiannular augment being formed from an augment material comprising at least one of a biologic material, a biologically absorbable material, and a combination of biologic and biologically absorbable materials; and

wherein the augment material is supplemented with at least one of an agent to promote the formation of scar tissue, a clotting agent, and an antibacterial agent; and

wherein the augment material is formulated not to transform into scar tissue.

2. The prosthetic device of claim 1, further comprising at least one fastener for mounting the semiannular augment to the acetabular cup assembly, the fastener being formed from a fastener

material selected from the group consisting of a biologic material, a biologically absorbable material, and a combination of biologic and biologically absorbable materials.

4. The prosthetic device of claim 2, wherein the fastener comprises at least one of:

a screw;

a snap;

a clip;

a keyway;

a dowel; and

a rivet.

5. The prosthetic device of claim 1, wherein the augment material includes at least one, or an equivalent, of:

extra cellular matrices (ECMs);

poliglecaprone 25;

polydioxanone;

surgical gut suture (SGS);

gut;

polyglactin 910;

human autograft tendon material;

collagen fiber;

poly-L-lactic acid (PLLA);

polylactic acid (PLA);

polylactides (Pla);

racemic form of polylactide (D,L-Pla);

poly(L-lactide-co-D,L-lactide);

polyglycolides (PGa);

polyglycolic acid (PGA);

polycaprolactone (PCL);

polydioxanone (PDS);

polyhydroxyacids; and

resorbable plate material.

6. The prosthetic device of claim 5, wherein the extra cellular matrices (ECMs) include at least one of:

porcine small intestine submucosa (SIS);

xenogeneic small intestine submucosa (xSIS);

urinary bladder submucosa (UBS);

laminated intestinal submucosa; and

glutaraldehyde-treated bovine pericardium (GLBP).

14. The prosthetic device of claim 2, wherein the semiannular augment includes at least one integrated fastener.

15. The prosthetic device of claim 14, wherein the integrated fastener includes a snap-on retention member enabling snap-on-type mounting of the semiannular augment to the acetabular cup assembly.

27. A hip prosthesis comprising:

an acetabular cup assembly to be fastened to a patient's pelvis, the acetabular cup assembly including:

an acetabular liner; and

an acetabular cup, the acetabular liner releasably engaging the acetabular cup to be permanently mounted to the patient's pelvis;

a femoral stem to be fastened to the patient's femur, the femoral stem including a ball component at its proximal end received within the acetabular liner to form a ball joint type coupling; and

a semiannular augment to be mounted to a distal end of the acetabular liner, adjacent to the ball component, wherein the semiannular augment assists in stabilizing the ball joint type coupling between the acetabular liner and the femoral stem by temporarily increasing the height of a portion of the rim of the acetabular liner, while enabling rotational and angular movement between the acetabular liner and the femoral stem;

the semiannular augment being formed from an augment material comprising at least one of a biologic material, a biologically absorbable material, and a combination of biologic and biologically absorbable materials; and

wherein the semiannular augment includes at least one integrated fastener; and

wherein the augment material is formulated not to transform into scar tissue.

28. The hip prosthesis of claim 27, wherein the fastener is formed from a fastener material selected from the group consisting of a biologic material, a biologically absorbable material, and a combination of biologic and biologically absorbable materials.

29. The hip prosthesis of claim 28, wherein the fastener material includes at least one, or an equivalent, of:

a poly-L-lactic acid material; and

collagen.

30. The hip prosthesis of claim 28, wherein the fastener comprises at least one of:

a screw;

a snap;

a clip;

a keyway;

a dowel; and

a rivet.

31. The hip prosthesis of claim 27, wherein the augment material includes at least one, or an equivalent, of:

extra cellular matrices (ECMs);

poliglecaprone 25;

polydioxanone;

surgical gut suture (SGS);

gut;

polyglactin 910;

human autograft tendon material;

collagen fiber;

poly-L-lactic acid (PLLA);

polylactic acid (PLA);

polylactides (Pla);

racemic form of polylactide (D,L-Pla);

poly(L-lactide-co-D,L-lactide);

polyglycolides (PGa);

polyglycolic acid (PGA);

polycaprolactone (PCL);

polydioxanone (PDS);

polyhydroxyacids; and

resorbable plate material.

32. The hip prosthesis of claim 31, wherein the extra cellular matrices (ECMs) include at least one of:

porcine small intestine submucosa (SIS);

xenogeneic small intestine submucosa (xSIS);

urinary bladder submucosa (UBS);

laminated intestinal submucosa; and

glutaraldehyde-treated bovine pericardium (GLBP).

37. The hip prosthesis of claim 27, wherein the augment material is supplemented with an agent to promote the formation of scar tissue.

38. The hip prosthesis of claim 27, wherein the augment material is supplemented with a clotting agent.

39. The hip prosthesis of claim 27, wherein the augment material is supplemented with an antibacterial agent.

(9) Evidence Appendix

None.

(10) Related Proceedings Appendix

None.

(11) Proposed Findings of Fact and Conclusions of Law

Question #1: Has the Examiner carried his burden to prove that claims 1, 2, 4-6, 14, 15, 27-32, and 37 fail to particularly point out and distinctly claim the subject matter of the invention pursuant to 35 U.S.C. § 112, second paragraph?

Answer #1: No. A rejection pursuant to 35 U.S.C. § 112, second paragraph, requires a *prima facie* showing by the Examiner that the claims, read in the light of the specification, do not reasonably apprise those skilled in the art both of the utilization and scope of the invention.[40] If the claim language is as precise as the subject matter permits, nothing more is required.[41]

In this circumstance, claims 1, 2, 4-6, 14, 15, 27-32, and 37 each include a pair of limitations requiring: (a) the augment material is formulated not to transform into scar tissue; and (2) the augment is supplemented with an agent to promote the formulation of scar tissue. These two limitations, when read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention. Specifically, the claim language is as precise as the subject matter appears to permit. Accordingly, the rejection of claims 1, 2, 4-6, 14, 15, 27-32, and 37 under 35 U.S.C. § 112, second paragraph, is REVERSED.

Question #2: Has the Examiner carried his burden to prove that claims 1, 2, 4-6, 14, 15, 27-32, and 37 fail to comply with the written description requirement of 35 U.S.C. § 112, first paragraph?

Answer #2: No. A rejection pursuant to 35 U.S.C. § 112, first paragraph, requires a *prima facie* showing by the Examiner reasonably explaining why the scope of protection provided by a claim is not adequately enabled by the disclosure.[42] "[I]t is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any

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[40] *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, (Fed. Cir. 1985) citing *Georgia-Pacific Corp. v. United States Plywood Corp.*, 258 F.2d 124, 136 (2nd Cir.), cert. denied, 358 U.S. 884 (1958).
[41] *Id.*
[42] *In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993).

statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure."[43]

Here, the Examiner has failed to carry his burden pursuant to 35 U.S.C. § 112, first paragraph, because he has not shown, by a preponderance of the evidence, that the claim element "wherein the augment is formulated not to transform into scar tissue" is new matter. In particular, the Examiner's single-sentence, conclusory allegations are woefully short of the required showing by a preponderance of the evidence. Further, the Examiner failed to properly respond to Appellant's rebuttal arguments as required by M.P.E.P. § 2163.04, thereby both denying Appellant an opportunity to fully confront the Examiner's reasoning and leaving a poor record for appeal.

Additionally, the application as originally filed adequately discloses an augment material that does not transform into scar tissue but contains an agent to promote scar tissue. Specifically, paragraphs [0044]-[0047] of the specification as originally filed disclose various materials that may be included in the augments and, as known to those of skill in the art, some of these materials promote the formation of scar tissue. At least the statement in paragraph [0040] noting that an exemplary embodiment of the invention "could also be formulated" so as to be replaced by tissue (such as scar tissue) inherently discloses that the augments could be "formulated not to transform into scar tissue." Accordingly, the application as originally filed properly supports the claim element in question and the 35 U.S.C. § 112, first paragraph, rejection of claims 1, 2, 4-6, 14, 15, 27-32, and 37 is REVERSED.

Question #3: Has the Examiner carried his burden to prove that claims 1, 2, 4-6, 14, 15, 27-32, and 37 are unpatentable over Klüber (DE 19716051) under 35 U.S.C. § 102(b)?

[43] *In re Marzocchi*, 439 F.2d 220, 224 (C.C.P.A. 1971).

Answer #3: No. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."[44]

Here, the Examiner has not shown that claims 1, 2, 4-6, 14, 15, 27-32, and 37 are anticipated by Klüber (DE 19716051) and, in fact, claims 1, 2, 4-6, 14, 15, 27-32, and 37 are not anticipated by Klüber because Klüber fails to disclose all of the claim elements.

Specifically, each of claims 1, 2, 4-6, 14, 15, 27-32, and 37 includes an element requiring that "the augment material is formulated not to transform into scar tissue." Nowhere does Klüber teach or suggest this claim element. Further, claims 1, 2, 4-6, 14 and 15 require, but Klüber does not disclose, an augment "supplemented with at least one of an agent to promote the formation of scar tissue, a clotting agent, and an antibacterial agent." Claims 27-32 and 37 require, but Klüber does not disclose, "the semiannular augment includes at least one integrated fastener." Where the cited reference does not teach all of the claim elements, a rejection cannot be made under 35 U.S.C. § 102(b). Accordingly, the rejections of claims 1, 2, 4-6, 14, 15, 27-32, and 37 under 35 U.S.C. § 102(b) are REVERSED.

Question #4: Has the Examiner carried his burden to prove that claims 1, 2, 4-6, 14, 15, 27-32, and 37 are unpatentable over Klüber alone, or in combination with Mikhail (US 5,549,701), under 35 U.S.C. § 103(a)?

Answer #4: No. A rejection under 35 U.S.C § 103(a) requires an unrebutted *prima facie* showing by the Examiner that the claims would have been obvious to one of skill in the art at the time of the invention.[45] Notably, the showing must be explicit[46] and must consider all words in the claims.[47] In addition, the Examiner must consider prior art that teaches away from the

[44] M.P.E.P. § 2131 (citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).
[45] *In re Rouffet*, 149 F.3d 1350, 47 U.S.P.Q.2d 1453 (Fed. Cir. 1998).
[46] *KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007).
[47] *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970).

claimed invention[48] and the departure of the claimed invention from the conventional wisdom in the art[49] as evidence of non-obviousness.

In this circumstance, the Examiner failed to consider the element of claims 1, 2, 4-6, 14, 15, 27-32, and 37 requiring that the augment material is "formulated not to transform into scar tissue." Further, the Examiner failed to consider the element of claims 27-32 and 37 that recites "the semiannular agument includes at least one integrated fastener." As consideration of all claim elements is required, the rejection of claims 1, 2, 4-6, 14, 15, 27-32, and 37 under 35 U.S.C. § 103(a) cannot stand.

In addition, Appellant has provided additional evidence of non-obviousness of the rejected claims. In particular, Klüber teaches away from the claimed invention and the claimed invention is a departure from the conventional wisdom in the art as exemplified by Klüber. Considering the prior art as a whole, this evidence of non-obviousness is persuasive.

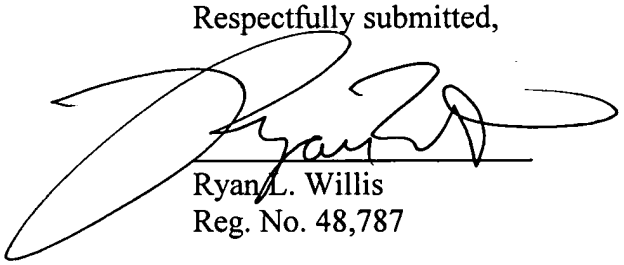
Accordingly, the rejection of claims 1, 2, 4-6, 14, 15, 27-32, and 37 under 35 U.S.C. § 103(a) is REVERSED.

[48] See *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165, 77 U.S.P.Q.2d 1865, 1870 (Fed. Cir. 2006).
[49] *In re Hedges*, 783 F.2d 1038, 228 USPQ 685 (Fed. Cir. 1986).

Conclusion

For the reasons discussed above, reversal of all of the rejections of record is respectfully requested.

Respectfully submitted,



Ryan L. Willis
Reg. No. 48,787

Taft, Stettinius & Hollister LLP
425 Walnut Street, Suite 1800
Cincinnati, OH 45202-3957
513-357-9663
willis@taftlaw.com